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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,644	01/15/2004	Peter Wernet	07588/026003	5815

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BOSTON, MA 02110

EXAMINER

NGUYEN, QUANG

ART UNIT PAPER NUMBER

1633

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/758,644	Applicant(s) WERNET, PETER	
	Examiner Quang Nguyen, Ph.D.	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 5-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 8/18/06 was entered.

Claims 1-3 and 5-9 are pending in the present application.

Claims 3 and 5-9 were withdrawn by Applicants.

Accordingly, amended claims 1-2 are examined on the merits herein.

Response to Amendment

The lack of Written Description rejection under 35 U.S.C. 112, first paragraph, was withdrawn in light of Applicant's amendment.

The Declaration under 37 CFR 1.132 filed 5/2/06 is sufficient to overcome the rejection of claims 1-2 based upon insufficiency of disclosure under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. ***This is a new ground of rejection.***

Claim 1 recites the limitation "said patient" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. This is because prior to this limitation, there is no recitation of any patient. For the purpose of a compact

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prosecution, the examiner interprets the term "said patient" broadly to be any patient for the prior art applied below.

Claim 2 is vague and indefinite in that the metes and bounds of the term "derived from" are unclear. It is unclear the nature and number of steps required to obtain a "derivative" of USSCs. The term implies a number of different steps that may or may not result in a change in the functional characteristics of USSCs from the source that it is "derived from". It would be remedial to amend the claim language to use the term "obtained from", which implies a more direct method of obtaining USSCs.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Naughton et al (US 5,842,477) as evidenced by Ha et al. (US 2005/0118714 A1). ***This is a new ground of rejection.***

The claims are directed to a method for treating a cardiac muscle disease, said method comprising administering to a patient human unrestricted somatic stem cells (USSCs), wherein said USSCs are negative for the CD14 and CD45 antigens and positive for the CD13 and CD29 antigens and lack expression of hyaluronan synthase.

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In examining these claims, Examiner does not give any patentable weight to the preamble because the body of these method claims contains a single step of administering to a patient human unrestricted somatic stem cells, and without any nexus to the preamble of the claims (e.g., a particular patient, and the resulting outcome).

Naughton et al teaches a method comprising implanting into a patient a biocompatible, non-living three-dimensional scaffold and at least a source of chondrocyte progenitor cells that includes human mesenchymal stem cells obtained from umbilical cord or placenta tissue or umbilical cord blood (see at least the abstract; col. 10, lines 60-67); col. 6, lines 36-42). The human mesenchymal stem cells obtained at least from umbilical cord blood as taught by Naughton et al. must be positive for the CD13 and CD29 antigens, while negative for the CD14 and CD45 antigens and lack expression of hyaluronan synthase as evidenced by the teachings of Ha et al. (paragraph 0027). Ha et al. teaches clearly that human umbilical cord-blood derived mesenchymal stem/progenitor cells have immunophenotypic characteristics in that they are positive for CD29, CD49e, CD44, CD54, CD13, CD90, SH2, SH3 and SH4 antigens and negative for CD45, CD34, CD14, HLA-DR, CD31, CD51/61, CD49d, CD106 and CD64 antigens.

Accordingly, the teachings of Naughton et al anticipate the instant claims as written.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Dave Nguyen, may be reached at (571) 272-0731.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.


QUANG NGUYEN, Ph.D.
PATENT EXAMINER